TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 07-24-87 OUT 11-24-87

Reviewed by Bruce H. Mann Bruce H. Mann 11-24-87 Date 11/24/87

EPA Reg. No. or File Symbol #211-36

EPA Petition or EUP No. None

Date Division Received 07/08/87

Type Product(s): Hospital Disinfectant

Data Accession No(s) 402607-01

Product Mgr. No. Pm-32 (Kempter)

Product Name(s) Tri-Cen Germicidal Deteergent

Company Name (s) Central chemical Co.,

Submission Purpose Response to Tuberculocidal Data Call-In Notice of May 1986.

Type Formulation Lquid concentrate to be diluted for use

Active Ingredient(s):	%
Sodium ortho benzyl-para-chlorophenate	4.40
Sodium ortho-phenylphenate	2.82
Sodium para-tertiary-ampylphenate	2.49

TB data

200.0 Introduction

200.1 Use(s)

Refer to the latest accepted label, dated 04-16-87, and the proposed label dated 07-24-87.

The current submission is in response to the Data Call-In Notice for Tuberculocidal Effectiveness from EPA dated 06-13-86. Also, the submission consists of an amendment for added use in mushroom farm premises with expanded labeling. Also, the submission consists of an amendment to change the tuberculocidal effectiveness from 1:100 for pre-clean surfaces to 1:128 in the presence of 5% moderate soil load.

200.3 Factors Affecting Amount/Type of Data Required

A. Efficacy data were previously submitted and accepted for this product to support a tuberculocidal claim, based on the following conditions:

Effectiveness as a tuberculocide (vs. Mycobacterium tuberculosis var. bovis) for a contact time of 10 minutes at $20^{0}C$ at a dilution of 1:100 when used to thoroughly wet previously, cleaned, hard, nonporous, inanimate surfaces.

Previous efficacy data submitted for this product post-dates current data and label requirements for tuberculocides, additional data are required.

B. Additional data are required to support the proposed change in the effective test dilution of 1:128 in the presence of 5% horse serum.

201.0 Data Summary(New data).

The data submitted in response to the Tuberculocidal Data Call-In Notice are new data submitted under Accession No. 402607-01

201.1 Brief description of Tests

Reports "Ref: #86-0732-11, #86-1419-11 and # 86-0456-11" (Tuberculocidal) dated 09-15-86, 01-20-87, and 07-06-87, by Barbara B. Colina, Susan Biecker and Glye K. Mulberry, HiLL Top BioLabs, Inc., Miamiville, Ohio 45147.

201.2 Test Summaries

a. Method: AOAC Tuberculocidal Method(II. Confirmative In Vitro Test for Determining Tuberculocidal Activity) Official Methods of Analysis, 14 th. ed., 1984.

b. Modifications: Tested the presence of 5% horse serum as per items 4 and 6 of DIS/TSS-2 Enclosure.

c. Samples: Lot #058616, #128531, rec'd 06-10-86;
#058616, rec'd 09-19-86; and
#028718 and #118620 rec'd 02-24-87

d. Exposure Time: 10 minutes at 20°C.

e. Dilution Tested: 1:128 .

f. Test Organism: Mycobacterium tuberculosis var. bovis(BCG). Phenol Resistance: No growht at 1:50 in 10 minutes; but growth at 1:75 in 10 minutes.

g. Neutralizer/Subculture Media: Modified Proskauer-Beck(MPB), Middlebrook 7H9 Broth(7H9) and Kirchner's Medium(KIR).

h. Incubation: 90 days at 37°C.

i. Results:

Test Organism	Test Sample	Test Dilution	Positive/Total Carriers MPB	7H9	KIR
M. bovis(BCG)	#058616 (Rec'd 6-10-86)	1:128(5% soil)	0/10	0/10	0/10
M. bovis(BCG)	#128531 (Rec'd 6-10-86)	1:128(5% soil)	0/10	1/10	1/10
M. bovis(BCG)	#058616 (Rec'd 9-19-86)	1:128(5% soil)	0/10	2/10	2/10
M. bovis(BCG)	#028718 (Rec'd 02-24-87)	1:128(5% soil)	0/10	0/10	0/10
M. bovis(BCG)	#118620 (Rec'd 02-24-87)	1:128(5% soil)	0/10	0/10	0/10

j. Control Survival Studies: The survival of the inoculum on the contaminated carriers showed acceptable levels of viable counts per carrier for the 5% horse soil load.

k. Conclusions: No failures reported with exposure of 10 minutes at 20°C for the 1:128 dilution in 5% horse serum, for batches #028718 and #118620; however, several failures(3) were reported for batches #128531 and #058616.

l. Comments: Tuberculocidal effectiveness at 1:128 in the presence of 5% horse serum are acceptable based on batches 028718 and 118620 for 10 minutes at 20°C; however, the data reports for batches 128531 and 058616 indicate that an exposure time of 10 minutes are not sufficient and should be increased to assure product effectiveness.

TECHNICAL SUPPORT SECTION REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol	# 252-36
Date Division Received	07-08-87
Data Accession No(s)	402607-01
Product Mgr. No	PM- 32 (Kempter)
Product Name(s)	Tri-Cen Germicidal Detergent
Company Name (s)	Central Chemical Co.,

202.0 Recommendations

202.1 Efficacy Supported by the Data

The submitted data do show effectiveness of the product as a tuberculocide by the AOAC Tuberculocidal Activity Method (II. Confirmative In Vitro Test) (modified) in 10 minutes at 20^0C at a dilution of 1:128 in the presence of 5% horse serum when used to thoroughly wet cleaned, hard, nonporous, inanimate, environmental surfaces.

Recommendations and Comments:

Eventhough the submitted tuberculocidal data based on products #028718 and #118620 are satisfactory, the applicant should be aware that several of the submitted batches failed to pass the Modified AOAC TB Procedure and showed inconsistent effectiveness. As such, it is recommended that the applicant label provides directions for use to include an increase in exposure time or cleaning directions to assure product effectiveness.

203.0 Labeling

In order to achieve the conditions necessary for tuberculocidal effectiveness, based on the above data, the direction for use for the proposed label dated 07-24-87 must be revised to reflect the following instructions:

1. Eventhough the product is effective in 5% horse serum, the use directions for the tuberculocidal claim should be provided with these wordings "The necessity for removal of heavy soil and gross filth, clean surface prior to application of product"

2. Under the use directions for the tuberculocidal claim, add these wordings "Effective in 10 minutes at 20^0C".

In lieu of the required directions for use and recommendations, delete the tuberculocidal claim.

3. Labeling pertaining to Mushroom Farm Premises:

No adverse comments.

Note to PM 32: The TSS(Efficacy), Disinfectants Branch, has no objection to the use of this product as a disinfectant on hard, inanimate surfaces in mushroom premises at the recommended dilution(s), it is apparant from the label claims for this use that it is intended control organisms associated with diseases of mushroom. Therefore, a review of this pattern of use against these organisms is deferred to TSS(Eficacy), Herbicides-Fungicides Branch, and Insecticides-Rodenticides Branch. The application for this use should be sent to them for review and comment on the claims.